Type 2 Diabetes Prevention in the Real World

Three-year results of the GOAL Lifestyle Implementation Trial

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OBJECTIVE — We study the effectiveness of the GOAL Lifestyle Implementation Trial at the 36-month follow-up.

RESEARCH DESIGN AND METHODS — Participants (n = 352, type 2 diabetes risk score FINDRISC = 16.2 ± 3.3, BMI 32.6 ± 5.0 kg/m^2) received six lifestyle counseling sessions over 8 months. Measurements were at baseline, 12 months (88.6%), and 36 months (77.0%).

RESULTS — Statistically significant risk reduction at 12 months was maintained at 36 months in weight (−1.0 ± 5.6 kg), BMI (−0.5 ± 2.1 kg/m^2), and serum total cholesterol (−0.4 ± 1.1 mmol/l).

CONCLUSIONS — Maintenance of risk reduction in this "real world" trial proves the intervention's potential for significant public health impact.

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The Goal Lifestyle Implementation Trial (1,2) replicated most of the findings from the Finnish Diabetes Prevention Study (DPS) (3,4) in primary health care settings, demonstrating that lifestyle counseling can be effective and feasible in routine care. We report findings on sustainability of the results at 3 years.

RESEARCH DESIGN AND METHODS

— This study was developed and evaluated as a "real world" implementation trial (5). We analyze risk factor changes from baseline to 3-year follow-up.

The intervention, with lifestyle change objectives drawn from the DPS (3), was delivered as six sessions of task-oriented sociobehavioral group counseling by public health nurses over a period of 8 months. The protocol included no other formal postintervention contact with the participants, except follow-up measurements at years 1 and 3.

A fully detailed description of the program content, recruitment, participant characteristics, and measures has been published previously (1). The study sample consisted of 352 participants (age 50–65 years, type 2 diabetes risk assessed by mean FINDRISC [6] score 16.2 ± 3.3), of whom 312 (88.6%) attended the measurements at year 1 and 271 (77.0%) at year 3. Eight participants responded at year 3 but not at year 1.

All clinical data at baseline, and years 1 and 3, were collected by study nurses. Demographic background data were self-reported in a baseline questionnaire. Outcomes included risk factor changes from baseline to years 1 and 3 (Table 1). Laboratory tests at year 3 were made and analyzed in local health care centers using the same methodology as at year 1 (1).

Differences between respondents and those lost to follow-up were analyzed with χ^2 tests and independent-samples t tests, risk factor changes from baseline to years 1 and 3 with paired-sample t tests, and the effect of medication use on cholesterol changes with a repeated-measures ANOVA. Computations were performed using the SPSS for Windows version 15.0.

Principles of the Declaration of Helsinki were followed. The ethics committee of Päijät-Häme Central Hospital reviewed the study protocol. All participants gave their informed consent for the study.

RESULTS

— Reduction in weight and BMI achieved by year 1 were maintained also at year 3 (Table 1). Improvement in blood lipids at year 3 was more pronounced than at year 1, but this was mainly attributed to the use of lipid-lowering medication (F = 63.135, P < 0.001 for medication use × total cholesterol interaction). Of the 193 participants with normal glucose tolerance at baseline, 10.9% had impaired glucose tolerance (IGT) and 1.6% had diabetes at year 3. Of the 65 participants who had had IGT at baseline, 12% had diabetes and 43% had returned to normal by year 3.

Participants who completed the study (n = 271) differed from participants who were lost to the 3-year follow-up (n = 81) in employment status (χ^2 = 6.447, P = 0.040), by being more often retired (50.0 vs. 39.5%) and less often unemployed (11.5 vs. 22.4%). At baseline, the completers also had a lower mean BMI (32.3 ± 5.0 vs. 33.7 ± 4.8 kg/m^2, t = 2.064, P = 0.040) and waist circumference (104.6 ± 12.3 vs. 107.9 ± 11.9 cm, t = 2.105, P = 0.036). At year 1, the differences did not yield significance (31.9 ± 4.9 vs. 33.1 ± 4.7 kg/m^2, NS, for BMI; 102.7 ±

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Table 1—*Changes in clinical and metabolic characteristics from baseline to years 1 and 3 in the GOAL Lifestyle Implementation Trial*

	Baseline	Change from baseline to year 1	Paired *t* test (df), *P*	Change from baseline to year 3	Paired *t* test (df), *P*
n	352	312		266	
Weight (kg)	90.0 ± 16.6	**−0.8 ± 4.5**	$t = 3.135$ (299), $P = 0.002$	**−1.0 ± 5.6**	$t = 3.042$ (261), $P = 0.003$
BMI (kg/m^2)	32.6 ± 5.0	**−0.3 ± 1.6**	$t = 2.988$ (299), $P = 0.003$	**−0.5 ± 2.1**	$t = 3.493$ (261), $P = 0.001$
Waist circumference (cm)	105.3 ± 12.3	**−1.6 ± 4.8**	$t = 5.528$ (291), $P < 0.001$	0.1 ± 6.4	NS
Fasting plasma glucose (mmol/l)	5.7 ± 0.8	**0.1 ± 0.6**	$t = 3.523$ (309), $P < 0.001$	0.0 ± 0.8	NS
2-h plasma glucose (mmol/l)	6.6 ± 1.7	0.1 ± 1.7	NS	0.1 ± 1.9	NS
Serum total cholesterol (mmol/l)	5.5 ± 1.0	**−0.1 ± 0.9**	$t = 2.133$ (311), $P = 0.034$	**−0.4 ± 1.1**	$t = 6.573$ (265), $P < 0.001$
Serum HDL cholesterol (mmol/l)	1.5 ± 0.4	−0.0 ± 0.3	NS	0.0 ± 0.3	NS
Serum total cholesterol–to–HDL cholesterol ratio	3.9 ± 1.0	−0.0 ± 0.8	NS	**−0.3 ± 1.5**	$t = 3.196$ (265), $P = 0.002$
Serum triglycerides (mmol/l)	1.6 ± 0.8	−0.07 ± 0.63	NS	**−0.14 ± 0.61**	$t = 3.745$ (265), $P < 0.001$

Data are mean change ± SD. Values in bold are statistically significant differences between measurement points.

11.9 vs. 105.6 ± 13.0 cm, NS, for waist circumference).

CONCLUSIONS — The GOAL Lifestyle Implementation Trial was designed to replicate results from efficacy trials such as the DPS (3,4), under more "real world" conditions with a more modest program delivered by existing health care personnel (1). Previously, we demonstrated that the model was reasonably successful in attaining many of the key lifestyle objectives. This longer-term follow-up has demonstrated that despite the relatively modest initial risk reduction (e.g., weight reduction at year 1 was only 0.8 kg in the GOAL trial compared with 4.5 kg in the DPS [3]), program maintenance was quite good. Between years 1 and 3, an average regain of 1 kg was found in the DPS, resulting in a −3.5 ± 5.1 kg weight reduction from baseline to 3 years (4), whereas in the GOAL trial, the weight decrease achieved at year 1 persisted throughout the follow-up. The same pattern was also evident in BMI. Improvement in blood lipids from baseline to 3 years was similar to the DPS. Conversion rate from IGT to diabetes (12% at year 3) is moderate compared with 9% in the intervention and 20% in the control group of the DPS (4). Furthermore, a significant number of participants reverted to normal glucose tolerance (<7.8 mmol/l) during the follow-up.

A single group pretest and posttest study design and use of the DPS findings from the same culture as a benchmark offers benefits that we have discussed earlier (1). The unemployed were more likely to drop out from the study during the postintervention follow-up, a factor limiting the conclusions that can be drawn of the long-term effectiveness of the intervention in this group of people.

A proportion of participants in any lifestyle intervention will fail to achieve change sufficient to significantly reduce clinical risks and will therefore also require pharmacological treatment. Blood lipid improvement after the first year was primarily attributable to prescription of lipid-lowering medication, suggesting that dyslipidemia was identified and could be effectively treated by the health care among those participants who had failed to make necessary or sufficient lifestyle changes.

Program intensity significantly correlates with weight loss (7). In the published efficacy trials, it has generally been greater than in our study, with contacts extending throughout the follow-up period (8,9). Such intensive interventions are likely limited to particularly high-risk groups. With the kind of intervention tested in our study, also those with a lower risk status could be targeted and much larger numbers of people reached. In the Päijät-Häme province, the program has now been integrated into the regional health care, where it is by default offered to all patients with elevated FINDRISC score (6). With systematic identification and counseling, this "low intensity, high reach" approach provides a potential for significantly improved population health.

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